FORM PTO-1390 (Modified) (REV 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
PG3604USW	
U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)	
09/889751	

INTERNATIONAL APPLICATION NO	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP99/09614	8 December 1999	22 January 1999

TITLE OF INVENTION
INHALATION DEVICE

APPLICANT(S) FOR DO/EO/US
Paul Kenneth RAND

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau)
   b. ☒ has been communicated by the International Bureau
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau)
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification
18. ☐ A change of power of attorney and/or address letter
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4)
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4)
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Copy of PCT Publication
Copy of PCT Request

Express Mail Label
EL395943178US

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
09/889751	PCT/EP99/09614	PG3604USW

24. The following fees are submitted:.	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
☐ Neither international preliminary examination fee (37 CFR 1 482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1000.00**		
☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$860.00**		
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$710.00**		
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$690.00**		
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$860.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$0.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	43 - 20 =	23	x $18.00	**$414.00**	
Independent claims	7 - 3 =	4	x $80.00	**$320.00**	
Multiple Dependent Claims **(check if applicable)**.			☐	**$0.00**	

TOTAL OF ABOVE CALCULATIONS =	**$1,594.00**	
☐ Applicant claims small entity status (See 37 CFR 1.27). The fees indicated above are reduced by 1/2.	**$0.00**	
SUBTOTAL =	**$1,594.00**	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1 492 (f)) +	**$0.00**	
TOTAL NATIONAL FEE =	**$1,594.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐	**$0.00**	
TOTAL FEES ENCLOSED =	**$1,594.00**	
	Amount to be: refunded	$
	charged	$

a. ☐ A check in the amount of _____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No **07-1392** in the amount of **$1,594.00** to cover the above fees A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **07-1392** A duplicate copy of this sheet is enclosed

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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23347
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James P. Riek
NAME

39,009
REGISTRATION NUMBER

July 25 2001
DATE

Express Mail Label
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Paul Kenneth RAND
International Application No.: PCT/EP99/09614
International Filing Date: 8 December 1999
Title: INHALATION DEVICE

Commissioner of Patents
Washington, D.C. 20231

FIRST PRELIMINARY AMENDMENT

Dear Sir:

The above identified application is being transmitted herewith for entry in the US National Phase under Chapter II of the PCT for the purpose of adding the priority information.

In the Abstract:

Please substitute the attached Abstract, which has been placed on a separate sheet of paper according to US practice, as required under 37 CFR 1.72(b)

In the Specification:

On the first line of the specification, after the Title, please add:

--This application is filed pursuant to 35 U.S.C. §371 as a United States National Phase Application of International Application No. **PCT/EP99/09614** filed **8 December 1999**, which claims priority from **GB9901282.5** filed **22 January 1999** in the United Kingdom and **GB9903342.5** filed **16 February 1999** in the United Kingdom--

In the Claims:

Claim 5 (Amended) Medicament cartridge according to Claim 1, wherein each medicament retainer comprises a pocket.

Claim 8 (Amended) Medicament cartridge according to Claims 1, wherein each medicament retainer comprises a hole in the carrier.

Claim 12 (Amended) Medicament cartridge according to Claim 10, wherein each medicament retainer comprises a cavity in the elongate carrier.

Claim 15 (Amended) Medicament cartridge according to Claim 1, wherein each medicament retainer is sized to retain a single dose of medicament.

Claim 24 (Amended) Inhalation device according to Claim 22, wherein each medicament retainer comprises a pocket in a first face of the disk.

Claim 28 (Amended) Inhalation device according to Claim 26, wherein each medicament retainer comprises a pocket.

Claim 40 (Amended) Inhalation device according to Claim 26 wherein said actuator comprises a piercer for piercably unsealing a medicament retainer.

Claim 42 (Amended) Inhalation device according to Claim 21, wherein said air outlet is provided with a mouthpiece.

Claim 43 (Amended) Use of an inhalation device according to Claim 21 for the administration of medicament to a patient.

REMARKS

Applicants have attached an abstract on a separate sheet of paper as required by US practice. Applicants have amended the specification for purposes of adding the priority information. Claims 5,8,12,15,24,28,40,42 and 43 have been amended to remove multiple dependencies. It is respectfully submitted that the present application is in condition for allowance. An early consideration and notice of allowance are earnestly solicited.

Respectfully submitted;

Date: 20 July 2001

By: _____
James P RIEK
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Marked-up Version of Amended Claims under §1.121

In the Claims:

Claim 5 (Amended) Medicament cartridge according to [any of] Claim[s] 1 [to 4], wherein each medicament retainer comprises a pocket.

Claim 8 (Amended) Medicament cartridge according to [any of] Claim[s] 1 [to 4], wherein each medicament retainer comprises a hole in the carrier.

Claim 12 (Amended) Medicament cartridge according to [either of] Claim[s] 10 [or 11], wherein each medicament retainer comprises a cavity in the elongate carrier.

Claim 15 (Amended) Medicament cartridge according to [any of] Claim[s] 1 [to 14], wherein each medicament retainer is sized to retain a single dose of medicament.

Claim 24 (Amended) Inhalation device according to [either of] Claim[s] 22[or 23], wherein each medicament retainer comprises a pocket in a first face of the disk.

Claim 28 (Amended) Inhalation device according to [either of] Claim[s] 26 [or 27], wherein each medicament retainer comprises a pocket.

Claim 40 (Amended) Inhalation device according to [any of] Claim[s] 26[-28 or 35] wherein said actuator comprises a piercer for piercably unsealing a medicament retainer.

Claim 42 (Amended) Inhalation device according to [any of] Claim[s] 21 [to 41], wherein said air outlet is provided with a mouthpiece.

Claim 43 (Amended) Use of an inhalation device according to [any of] Claim[s] 21 [to 42] for the administration of medicament to a patient.

INHALATION DEVICE

ABSTRACT

There is provided a medicament cartridge for use in an inhalation device comprising a carrier having a plurality of medicament retainers in a spiral path arrangement. Typically, the carrier is substantially planar. In one embodiment the carrier comprises an elongate carrier storable in a flat spiral configuration and extendable as a helix.

There is also provided an inhalation device comprising a housing having an air inlet, an air outlet, an airway therebetween and a medicament carrier having a plurality of medicament retainers in a spiral path arrangement. A mover is provided for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

Inhalation device

The present invention relates to a medicament cartridge for an inhalation device for use in the administration of medicament to a patient. The cartridge has a plurality of medicament retainers in a spiral path arrangement.

The use of inhalation devices in the administration of medicaments, for example in bronchodilation therapy, is well known. Such devices generally comprise a body or housing within which a medicament container is located. A mouthpiece (or nozzle) is typically provided, wherein 'in use' the mouthpiece communicates with the medicament container to allow passage of medicament from the source to the mouthpiece and thence, to the patient.

In a typical dispensing operation the body of the device is held by the patient and the mouthpiece (or nozzle) of the inhalation device is placed in the mouth (or nose) of the patient. The patient inhales, thereby causing transfer of medicament from the medicament container to the interior of the body of the patient.

It is desirable that the inhalation device is able to provide a plurality of doses of medicament. Known devices include metered dose inhalers having an aerosol container comprising sufficient medicament to provide plural individual doses. Also known are dry powder inhalers having a reservoir of dry powder from which individual doses may be delivered.

Other known devices have a medicament carrier having plural individual medicament retainers thereon. One such carrier is shaped in the form of a rigid disc having plural medicament-containing blisters arranged in a circular configuration thereon. Typically, such discs are designed to provide from five to

ten doses. Another such carrier has an elongate tape carrier having plural medicament-containing blisters arranged in a line along the length of the tape. The tape is generally retained on a spindle and the tape is progressively unwound from the spindle to allow access to individual blisters. Typically, such tape carriers are designed to provide about forty to sixty doses.

There is continuing interest in the design of medicament cartridges capable of providing very large numbers of individual doses. However, there is also a desire to reduce the size of the device, and hence the cartridge, so that it is readily portable by the patient. It will be appreciated that with the above described known carriers increasing the number of doses will also result in an inevitable and undesirable increase in the required size of disc and tape-winding on the spindle.

The Applicants have found that the use of a medicament cartridge comprising a carrier having a plurality of individually accessible medicament retainers in a spiral path arrangement allows for the provision of large numbers of doses from a single cartridge, whilst enabling the size of the cartridge to be kept at an acceptable level.

The Applicants have also found that the use of a medicament carrier comprising an elongate carrier having a plurality of individually accessible medicament retainers, wherein the carrier is storable in a flat spiral configuration and extendable for dispensing as a helix, allows for the provision of large numbers of doses from a single carrier, whilst enabling the size of the carrier and device to be kept at an acceptable level.

WO95/16483 describes an inhalation device comprising a housing, which houses a cylindrical container. The container has a number of helically arranged compartments, each of which contains a dose of powdered medicament. To

allow for dosing of medicament, the container is rotated thereby bringing a compartment into communication with an airway. The airway communicates with an air inlet through which the patient inhales, which inhalation causing passage of medicament from the compartment through the airway to the air inlet.

According to one aspect of the present invention there is provided a medicament cartridge for use in an inhalation device comprising a carrier having a plurality of medicament retainers in a spiral path arrangement. The spiral path is preferably a flat (i.e. two-dimensional) spiral path.

The carrier may be formed from any suitable material including plastic materials. Preferably, the carrier is substantially planar. More preferably, the carrier is substantially rigid. Preferably, the carrier is circular in shape and is rotationally mountable.

The medicament retainers are sized and shaped for retention of medicament. Each retainer may, for example, be a medicament-retaining pocket. Suitable pocket forms include a cavity (recess) provided in the retainer, a cup having sidewalls standing proud from the carrier and any composite of these cavity/cup forms. A cover, preferably a hermetically sealing cover may be provided to the pocket.

In one preferred aspect, each medicament retainer comprises a pocket in the carrier. Preferably, a seal is provided to each pocket. In a particularly preferred aspect, the seal comprises a sealing tape arranged along said spiral path and each pocket is accessible by progressive removal of the tape from the spiral path.

In another preferred aspect, each medicament retainer comprises a hole in the carrier. Each hole may be provided with a mesh for retention of medicament.

The mesh may be formed of any suitable materials including plastic materials. Covers, preferably hermetically sealing covers may be provided to seal the hole.

In a further aspect, the carrier is elongate, storable in a flat spiral configuration and extendable as a helix. Preferably, the medicament retainers are serially arranged along the elongate carrier. The elongate carrier is, for example a tape carrier.

Preferably, each medicament retainer comprises a cavity in the elongate carrier. Typically, a seal is provided to each cavity. More preferably the seal comprises a sealing tape and each cavity is individually accessible by peelable removal of the sealing tape.

The medicament retainers are sized and shaped for retention of medicament. Each retainer may, for example, be a medicament-retaining pocket. Suitable pocket forms include a cavity (recess) provided in the retainer, a cup having sidewalls standing proud from the carrier and any composite of these cavity/cup forms. A cover, preferably a hermetically sealing cover, may be provided to the pocket.

Preferably, each medicament retainer is sized to retain a single dose of medicament. More preferably, the medicament carrier has from 60 to 500, preferably from 100 to 300, medicament retainers.

The medicament doses may be applied to the carrier by any suitable method including wet and dry printing methods. Suitable wet printing methods include ink jet printing. Suitable dry printing methods include xerographic and electrostatic printing methods.

In use one or more of the medicament retainers are charged with medicament.

In one aspect, there is provided a medicament cartridge comprising a carrier having a plurality of medicament doses thereon, wherein said doses are in a spiral path arrangement.

In another aspect, there is provided a medicament carrier for use in an inhalation device comprising an elongate carrier having a plurality of medicament doses thereon, wherein said elongate carrier is storable in a flat spiral configuration and extendable as a helix.

According to another aspect of the present invention there is provided an inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

a medicament carrier having a plurality of medicament retainers in a spiral path arrangement; and

a mover for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

Preferably, the medicament carrier is a substantially rigid circular disc, which is rotatable relative to the housing.

In one aspect, the circumference of the circular disc is provided with teeth and said teeth engage a worm drive for drivable rotation of the disc.

In one aspect, each medicament retainer comprises a pocket in a first face of the disc. Preferably, the second face of the disc has a spiral track for receipt of a

tracking pin fixedly mounted on the housing such that as the disc rotates relative to the housing the tracking pin moves along the spiral track and the disc moves translationally relative to the housing.

According to a yet further aspect of the present invention there is provided an inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

a medicament carrier having a plurality of medicament retainers in a spiral path arrangement, each medicament retainer having a seal;

an actuator for progressively unsealing each medicament retainer on the spiral path.

Preferably, the device additionally comprises a mover for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

Preferably, each medicament retainer comprises a pocket.

Preferably, said seal comprises a sealing tape arranged along said spiral path and wherein each pocket is serially accessible by peelable removal of the tape.

Preferably, an end of said sealing tape connects to said actuator and peelable removal of the sealing tape is achievable by movement of the actuator.

In one aspect, the actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator. Preferably, the actuator is an axially mounted tapered pole.

According to a further aspect of the present invention there is provided an inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of medicament retainers, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to successively move each medicament retainer to an access position.

Preferably, each medicament retainer comprises a cavity in the elongate carrier.

Preferably, each medicament retainer has a seal, the device additionally comprising an actuator for unsealing a medicament retainer at the access position.

In one aspect, the seal comprises a sealing tape arranged along the elongate carrier and wherein each successive cavity is accessible by peelable removal of the tape from the elongate carrier. More preferably, an end of said sealing tape connects to the actuator and peelable removal of the sealing tape is achievable by movement of the actuator relative to the elongate carrier.

Preferably, the mover is rotatable relative to the housing such that rotation of the mover results in coiling of the elongate carrier around the mover, and also said actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator.

Preferably, the mover is an axially mounted tapered pole and the actuator is also an axially mounted tapered pole.

In another aspect, the actuator comprises a piercer for piercably unsealing a medicament retainer.

According to a still further aspect of the present invention there is provided an inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of doses thereon, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to serially move each dose to an access position.

Preferably, the air outlet is provided with a mouthpiece. Herein the term 'mouthpiece' is used in a generic sense to mean an element shaped such as to be insertable into the mouth or nose of a patient for inhalation therethrough.

Preferably, the device is provided with a dose counter, which indicates the number of doses dispensed from or remaining in the container. More preferably, the dose counter comprises an indexing mechanism actuated by a predetermined movement of the medicament container relative to the body.

Preferably, the medicament is in dry-powder form.

According to a still further aspect of the present invention there is provided the use of an inhalation device as described herein for the administration of medicament to a patient.

Preferred embodiments of the present invention will now be described with reference to the accompanying drawings in which:

Fig. 1a is a view of the top a medicament cartridge in accord with the present invention;

Fig. 1b is a view of the reverse medicament cartridge of Fig. 1a;

Fig. 2 is an exploded view of a cassette incorporating the medicament cartridge of Fig. 1a and 1b;

Fig. 3 is an exploded view of an inhalation device incorporating the cassette of Fig. 2;

Fig. 4a is a simplified plan view of the drive system of the inhalation device of Fig 3;

Fig. 4b is a simplified plan view of the mouthpiece slider of the inhalation device of Fig 3;

Fig. 5 is a plan view of the inhalation device of Fig 3 in assembled form;

Fig. 6 is a view of the top of a second medicament cartridge in accord with the present invention;

Fig. 7 is a view of a medicament carrier in accord with the present invention in the flat spiral storage configuration;

Fig. 8 is a view of the medicament carrier of Fig. 7 in the helically extended configuration;

Fig. 9 is an exploded view of a medicament cartridge suitable for containing a medicament carrier of the type depicted in Fig. 7;

Fig. 10 is a view of the medicament cartridge of Fig. 9 in assembled form and loaded with a medicament carrier.

Figs. 1a and 1b show a medicament cartridge in the form of a rigid disc 10 having teeth 11 on the circumference thereof. The top face 12 of the disc 10 is provided with a plurality of medicament retaining cavities 14 in a spiral path arrangement. The reverse face 16 of the disc 10 is provided with a spiral-tracking groove 18 and a centrally located peg 19 to enable the disc to be mounted for rotation.

Fig 2. shows an exploded view of a cassette incorporating the medicament cartridge of Figs. 1a and 1b. The cassette has a bottom cover 20 having peripheral walls 22 extending partially therearound. The bottom cover 20 is provided with a slit 24 for receipt of the peg 19 on the reverse face 16 of the disc 10. The bottom cover 20 is also provided with a tracking pin 26, which is located adjacent to a first end of the slit 24. When the cassette is in assembled form the tracking pin 26 follows the spiral tracking groove 18 on the reverse face 16 of the disc cartridge 10. The top cover 30 of the cassette is provided with an exit hole 32 located to register with successive medicament retaining cavities 14 on the top face 12 of the disc 10. The top cover 30 is also provided with a window 34.

To enable access to successive medicament retainers (doses) in use, it may be understood that the disc 10 will be rotated to bring each successive medicament-retaining cavity 14 into registration with the exit hole 32. The tracking pin 26 will follow the spiral tracking groove 18 thereby causing the disc 10 to be translationally shifted in a direction set by the slit 24 in the bottom cover 20 of the cassette. The view through the window 34 may thus be used as an indicator of the number of doses remaining.

Fig. 3 shows an exploded view of an inhalation device incorporating the cassette of Fig. 2. The device may be seen to comprise an outer casing having first 40 and second 50 interlocking portions.

The first portion 40 is provided with a window 42, which is positioned, for registration with the window 34 on the cassette. The first portion 40 of the casing is also seen to have a raised part 44 provided with a generally rectangular opening 46 which is shaped for receipt of mouthpiece 60. The mouthpiece may be seen to have a housing defining an airway 62, which is of generally rectangular shape. The airway 62 is provided with an entrance hole (not shown) which, when the mouthpiece is in the in-use position, communicates with the exit hole 32 in the top cover of the cassette thereby allowing transfer of medicament from a cavity 14 in the disc 10 through to the airway 62. The housing is also provided with two arms 64, 66 having racks 65 thereon.

The second portion 50 of the casing is shaped for receipt of mouthpiece slider 70 (shown in more detail in Fig. 4a) which is slidably movable within the second portion 50 of the casing. The mouthpiece slider 70 is provided with racks 72, 73 which communicate via transfer wheels 82, 83 on the main body 80 (shown in more detail in Fig. 4b) with the racks 65, 67 on the arms 64, 66 of the mouthpiece 60. It may thus be seen that slidable movement of the mouthpiece slider 70 enables the mouthpiece 60 to be moved from a storage position within

the casing to an in-use position in which it protrudes from the casing. The mouthpiece slider 70 is also provided with a hinged door 74 which may be seen to be movable from a closed position when the mouthpiece 60 is in the storage position to an open position as the mouthpiece 60 is moved to the in-use position.

The main body 80 may be seen to be shaped for receipt of the cassette and cartridge disc 10 contained therein. Referring to Fig. 4b, the main body includes a drive system for driving the rotation of the disc 10 within the cartridge. The drive system comprises an indexing screw 84, which communicates with the teeth 11 on the circumference of the disc 10 and with drive shaft 86. A fixed wheel 88 is provided to the central portion of the drive shaft 86. Rotation of the disc may be seen to be achievable by a user driven (e.g. by a thumb movement) rotation of the fixed wheel 88 and drive shaft 86 which causes rotation of the indexing screw 84 and hence rotation of the disc 10.

The fixed wheel 88 on the drive shaft 86 may also be seen to communicate with raised toothed portion 76 on the mouthpiece slider 70 such that the rotation of the fixed wheel 88 drives the slidable motion of the mouthpiece slider 70 and hence, translates into movement of the mouthpiece 60.

Fig. 5 shows a view of the inhalation device of Fig 3. in assembled form with the mouthpiece 60 in the storage position. It may be seen that the window 42 enables the user to view the position of the disc 10 and hence, to gain information about the number of doses remaining.

It will be appreciated that variations of the cartridge, cassette and inhalation device of Figs. 1a to 5 are possible. In particular, other drive systems for driving the rotation of the disc may be envisaged. The drive systems may be driven

directly by the user or by electrically powered means. Inhalation devices having a fixed mouthpiece are envisaged.

In one variation (not shown) the tracking groove 18 in the reverse face 16 of the disc 10 is provided with indentations spaced at positions aligned with the positions of the medicament retaining cavities 14 on the top face 12 of the disc 10. The so-indented tracking groove 18 can thus function as a rack which may be driven by a suitably configured pinion drive to achieve the rotation of the disc 10.

Fig. 6 shows a second medicament cartridge in the form of a rigid disc 110 having teeth 111 on the circumference thereof. The top face 112 of the disc 110 is provided with a plurality of medicament retaining pockets 114 in a spiral path arrangement. A peelably removable sealing tape 115 is arranged along the spiral path. The tape 115 acts such as to seal the pockets 114. As shown, part of the sealing tape 115 has been drawn from the top face 112 of the rigid disc 110 to reveal some of the pockets 114 on the outermost part of the spiral. It may thus be appreciated that each pocket 114 on the spiral path is serially accessible (i.e. each in turn) by peelable removal of the tape 115.

When the second medicament cartridge is incorporated into an inhalation device, the free end of the sealing tape 115 is connected to an actuator. Peelable removal of the sealing tape 115 is achieved by movement of the actuator. Typically, the actuator is rotatable and rotation of the actuator results in coiling of the sealing tape 115 around the actuator. The actuator may be an axially mounted tapered pole.

Fig. 7 shows a medicament carrier in the form of a tape 200 arranged in a flat spiral storage configuration. The tape 200 is provided with a plurality of medicament retaining cavities 214. The leading end 205 of the tape is shown

extended from the storage configuration making it available for feeding into an access station of an inhalation device (not shown) where the medicament retainers 214 may be successively accessed. An airway will link the access station to a mouthpiece through which the patient inhales, thereby enabling inhalation of medicament.

Fig 8. shows the medicament carrier tape of Fig 7 with the tape 200 near fully expanded from the flat spiral storage configuration into a helical configuration.

In one aspect, the tape 200 is housed in the storage configuration in a flat circular medicament cartridge, which is loadable into an inhalation device for dispensing therefrom. Fig 9 shows an exploded view of a suitable flat circular cartridge having a bottom circular cover 220 with peripheral walls 222 extending therearound and a top cover 230. The top cover 230 of the cartridge is provided with an exit slit 232, which is sized and shaped to receive the leading end 205 of the tape 200.

Fig. 10 shows the flat circular cartridge of Fig 9 in assembled form and loaded with a medicament carrier tape. The leading end 205 of the tape protrudes from the exit slit 232 in the top cover 230 of the cartridge. When loaded into an inhalation device, the leading end 205 of the tape is progressively fed into a medicament access station to enable access to successive medicament retainers. The inhalation device will typically include a drive mechanism connected to the leading end 205 of the tape 200 to drivably encourage the tape towards the medicament access station. The drive mechanism may be manually actuable or it may be powered electrically.

The medicament carrier, cartridge and inhalation device herein is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics,

e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro-α-[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclometasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

CLAIMS:

1. Medicament cartridge for use in an inhalation device comprising a carrier having a plurality of medicament retainers in a spiral path arrangement.

2. Medicament cartridge according to Claim 1, wherein said carrier is substantially planar.

3. Medicament cartridge according to Claim 2, wherein said carrier is substantially rigid.

4. Medicament cartridge according to Claim 3, wherein said carrier is circular in shape and is rotationally mountable.

5. Medicament cartridge according to any of Claims 1 to 4, wherein each medicament retainer comprises a pocket.

6. Medicament cartridge according to Claim 5, wherein a seal is provided to each pocket.

7. Medicament cartridge according to Claim 6, wherein said seal comprises a sealing tape arranged along said spiral path and wherein each pocket is accessible by progressive removal of the tape from the spiral path.

8. Medicament cartridge according to any of Claims 1 to 4, wherein each medicament retainer comprises a hole in the carrier.

9. Medicament cartridge according to Claim 8, wherein each hole is provided with a mesh for retention of medicament.

10. Medicament cartridge according to Claim 1 wherein said carrier is elongate, storable in a flat spiral configuration and extendable as a helix.

11. Medicament cartridge according to Claim 10, wherein said medicament retainers are serially arranged along the elongate carrier.

12. Medicament cartridge according to either of Claims 10 or 11, wherein each medicament retainer comprises a cavity in the elongate carrier.

13. Medicament cartridge according to Claim 12, wherein a seal is provided to each cavity.

14. Medicament cartridge according to Claim 13, wherein said seal comprises a sealing tape and each cavity is individually accessible by peelable removal of the sealing tape.

15. Medicament cartridge according to any of Claims 1 to 14, wherein each medicament retainer is sized to retain a single dose of medicament.

16. Medicament cartridge according to claim 15, having from 60 to 500, preferably from 100 to 300, medicament retainers.

17. Medicament cartridge according to Claim 16, wherein said medicament dose is applied to the carrier by wet or dry printing methods.

18. Medicament cartridge according to Claim 17, wherein medicament is present in one or more of the medicament retainers.

19. Medicament cartridge for use in an inhalation device comprising a carrier having a plurality of medicament doses thereon, wherein said doses are in a spiral path arrangement.

20. Medicament cartridge for use in an inhalation device comprising an elongate carrier having a plurality of medicament doses thereon, wherein said elongate carrier is storable in a flat spiral configuration and extendable as a helix.

21. Inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

a medicament carrier having a plurality of medicament retainers in a spiral path arrangement; and

a mover for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

22. Inhalation device according to Claim 21, wherein said medicament carrier is a substantially rigid circular disk which is rotatable relative to the housing.

23. Inhalation device according to Claim 22, wherein the circumference of said disk is provided with teeth and said teeth engage a worm drive for drivable rotation of said disk.

24. Inhalation device according to either of Claims 22 or 23, wherein each medicament retainer comprises a pocket in a first face of the disk.

25. Inhalation device according to Claim 24, wherein the second face of the disk has a spiral track for receipt of a tracking pin fixedly mounted on the housing such that as the disk rotates relative to the housing the tracking pin moves along the spiral track and the disk moves translationally relative to the housing.

26. Inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

a medicament carrier having a plurality of medicament retainers in a spiral path arrangement, each medicament retainer having a seal;

an actuator for progressively unsealing each medicament retainer on the spiral path.

27. Inhalation device according to Claim 26, additionally comprising a

a mover for moving the medicament carrier relative to the housing so as to bring successive medicament retainers individually into communication with the airway.

28. Inhalation device according to either of Claims 26 or 27, wherein each medicament retainer comprises a pocket.

29. Inhalation device according to Claim 28, wherein said seal comprises a sealing tape arranged along said spiral path and wherein each pocket is serially accessible by peelable removal of the tape.

30. Inhalation device according to Claim 29, wherein an end of said sealing tape connects to said actuator and peelable removal of the sealing tape is achievable by movement of the actuator.

31. Inhalation device according to Claim 30, wherein said actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator.

32. Inhalation device according to Claim 31, wherein the actuator is an axially mounted tapered pole.

33. Inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of medicament retainers, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to successively move each medicament retainer to an access position.

34. Inhalation device according to Claim 33, wherein each medicament retainer comprises a cavity in the elongate carrier.

35. Inhalation device according to Claim 34, wherein each medicament retainer has a seal, the device additionally comprising

an actuator for unsealing a medicament retainer at the access position.

36. Inhalation device according to Claim 35, wherein said seal comprises a sealing tape arranged along the elongate carrier and wherein each successive cavity is accessible by peelable removal of the tape from the elongate carrier.

37. Inhalation device according to Claim 36, wherein an end of said sealing tape connects to said actuator and peelable removal of the sealing tape is achievable by movement of the actuator relative to the elongate carrier.

38. Inhalation device according to Claim 37, wherein said mover is rotatable relative to the housing such that rotation of the mover results in coiling of the elongate carrier around the mover, and wherein said actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator.

39. Inhalation device according to Claim 38, wherein the mover is an axially mounted tapered pole and the actuator is also an axially mounted tapered pole.

40. Inhalation device according to any of Claims 26 - 28 or 35 wherein said actuator comprises a piercer for piercably unsealing a medicament retainer.

41. Inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of doses thereon, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to serially move each dose to an access position.

42. Inhalation device according to any of Claims 21 to 41, wherein said air outlet is provided with a mouthpiece.

43. Use of an inhalation device according to any of Claims 21 to 42 for the administration of medicament to a patient.

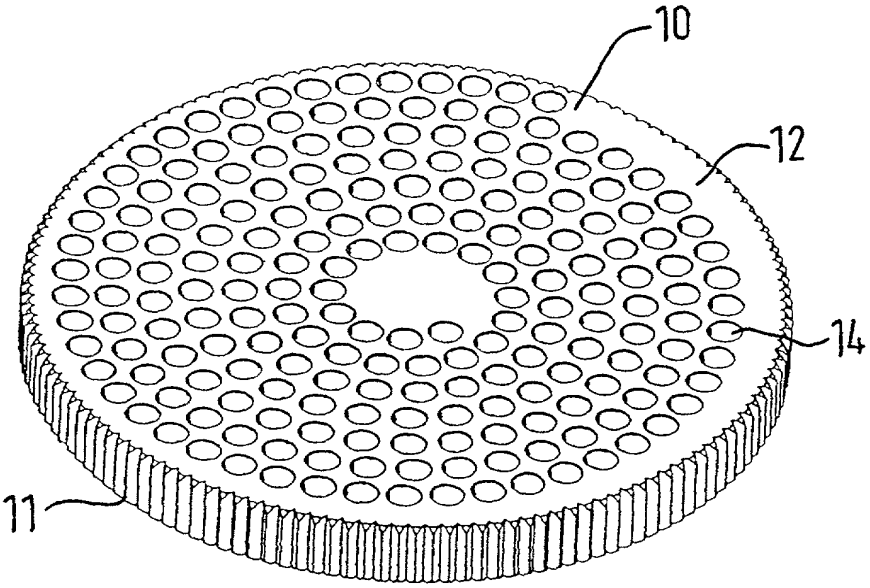

FIG.1a

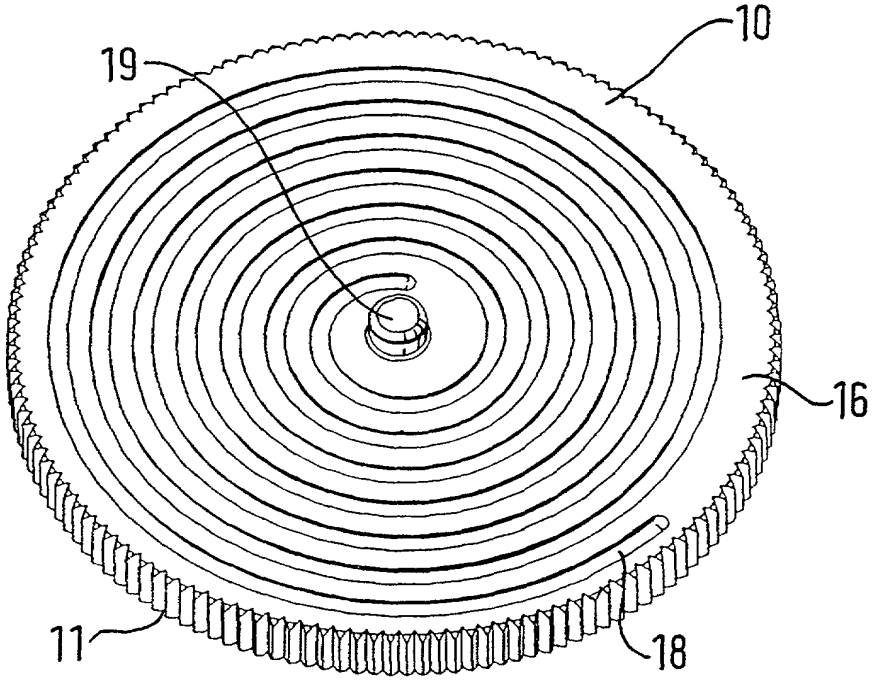

FIG.1b

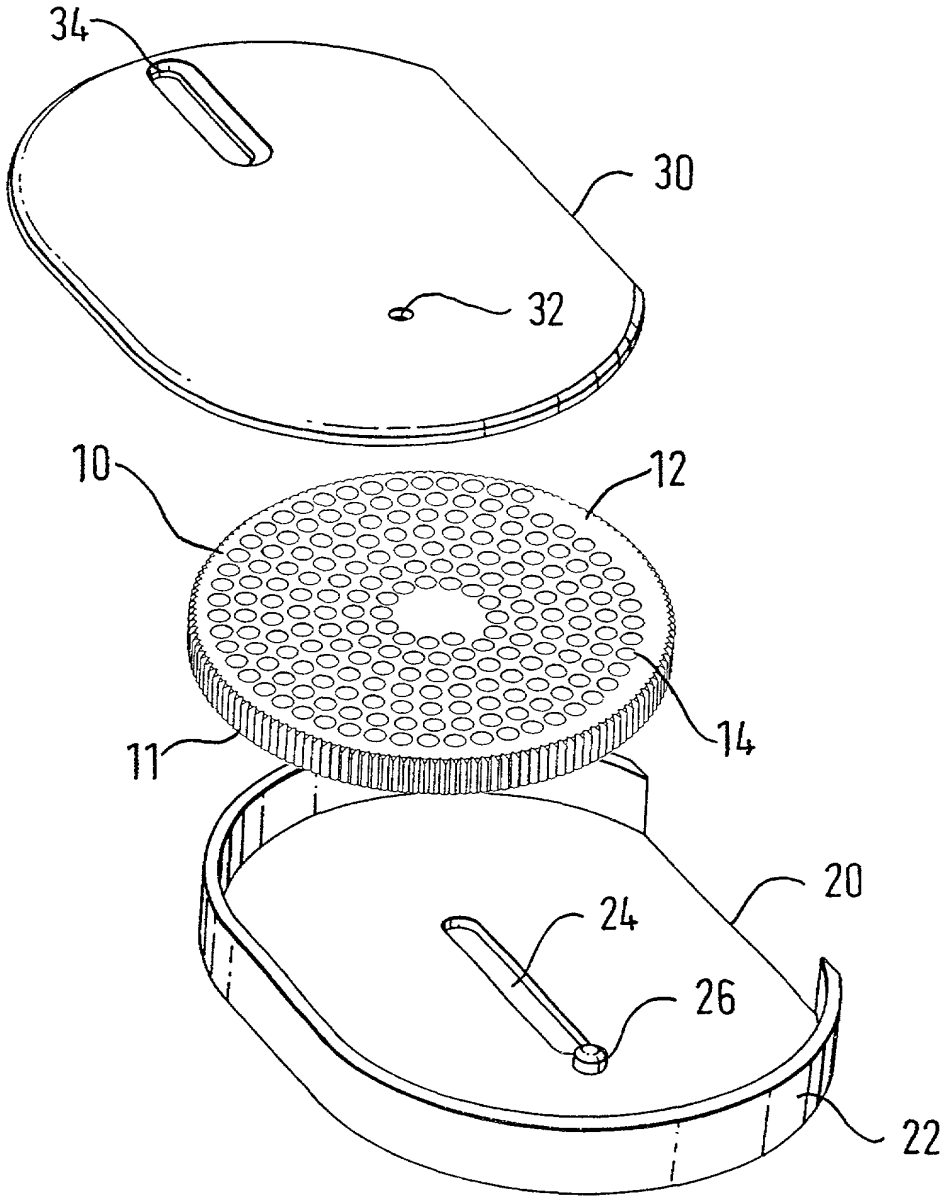

FIG. 2

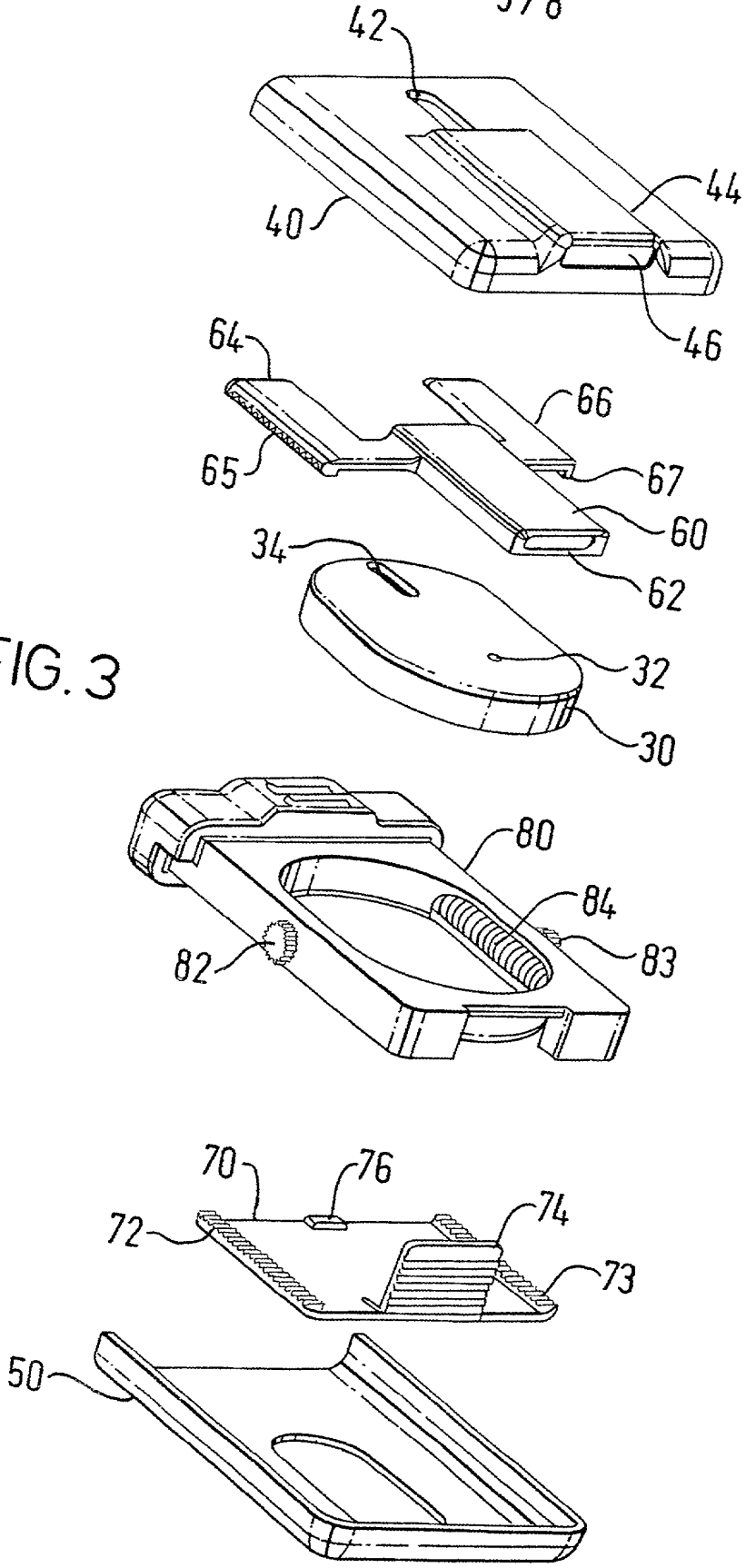

FIG. 3

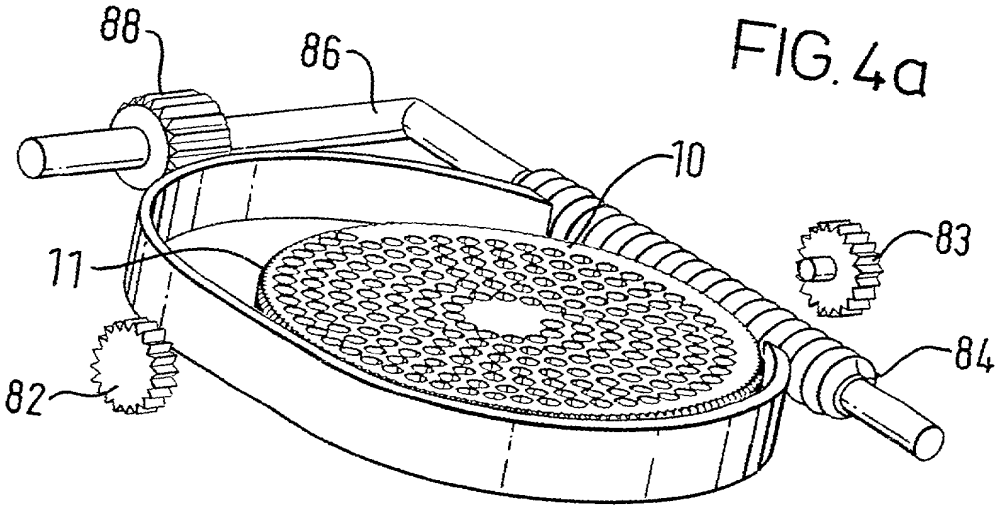

FIG. 4a

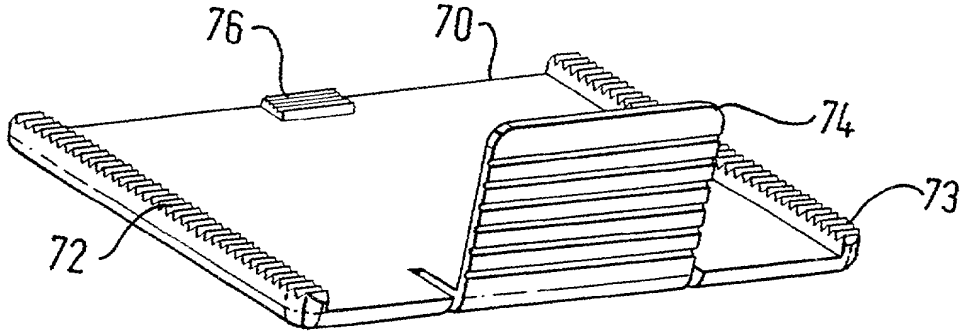

FIG. 4b

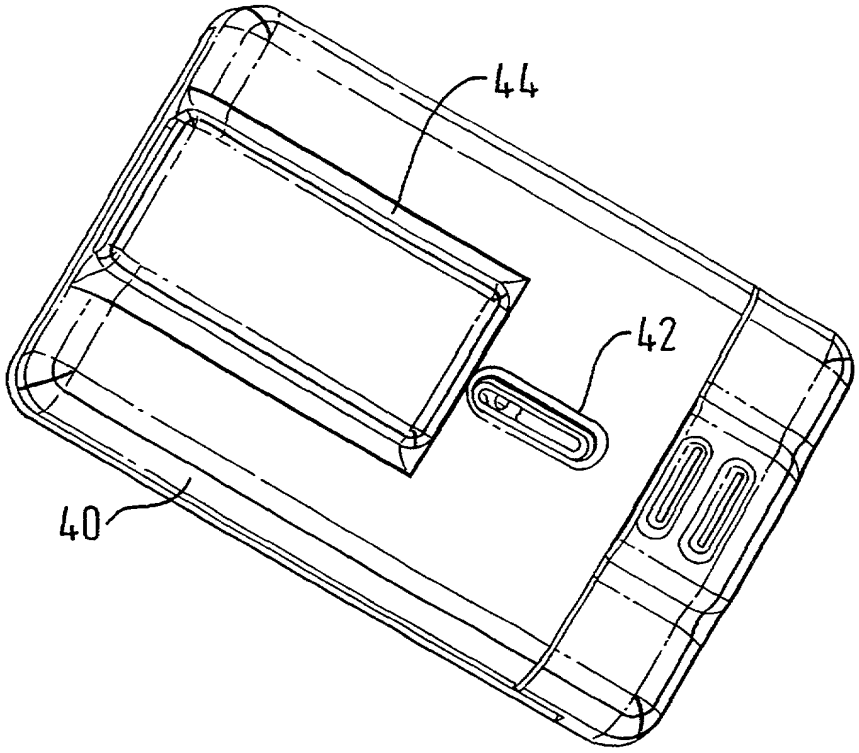

FIG. 5

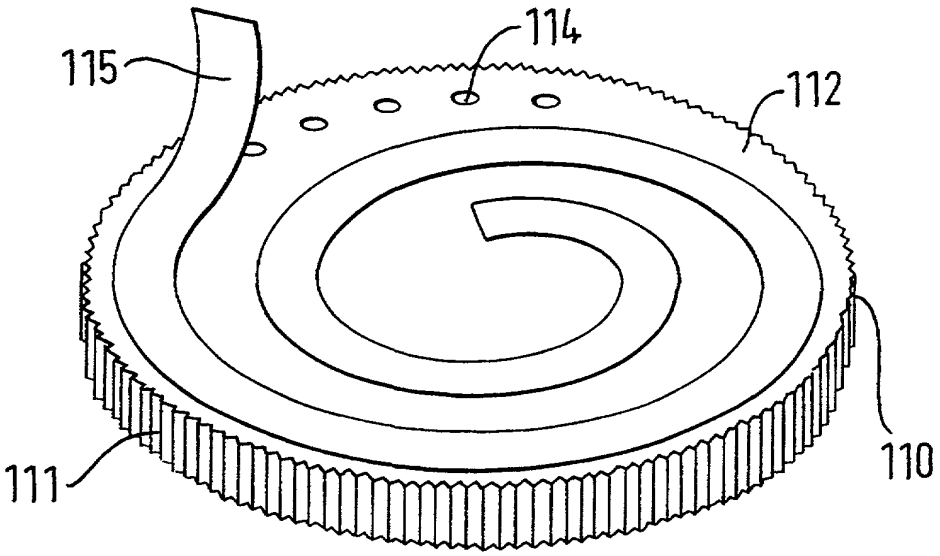

FIG. 6

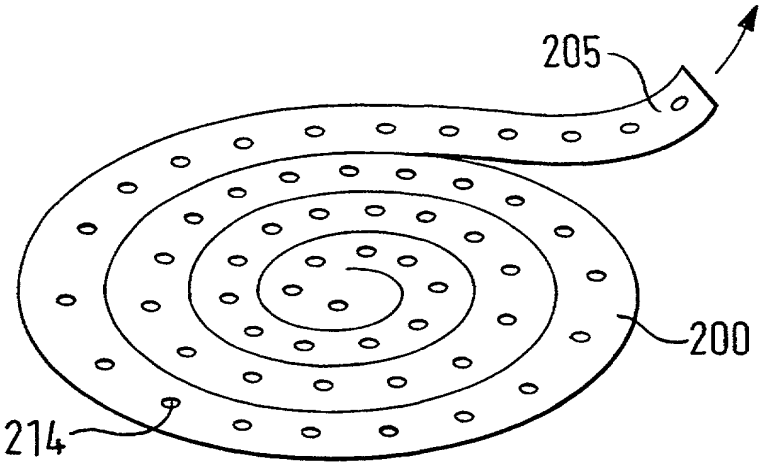

FIG. 7

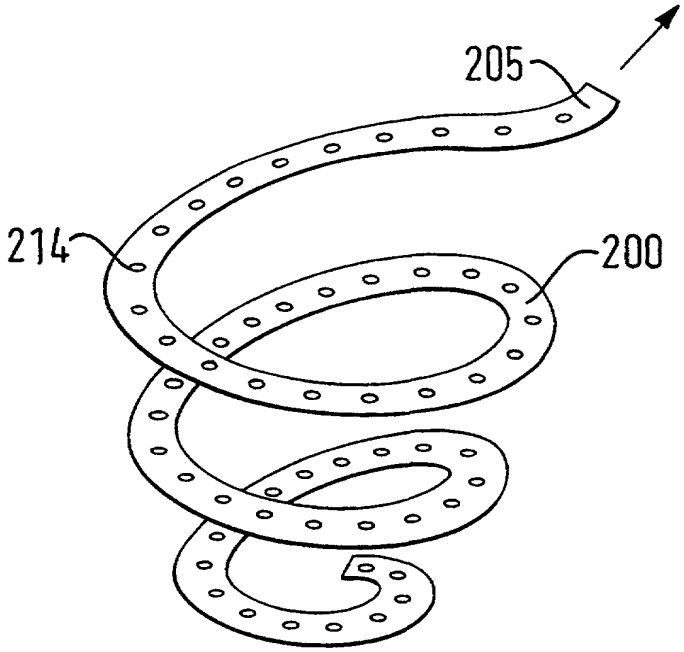

FIG. 8

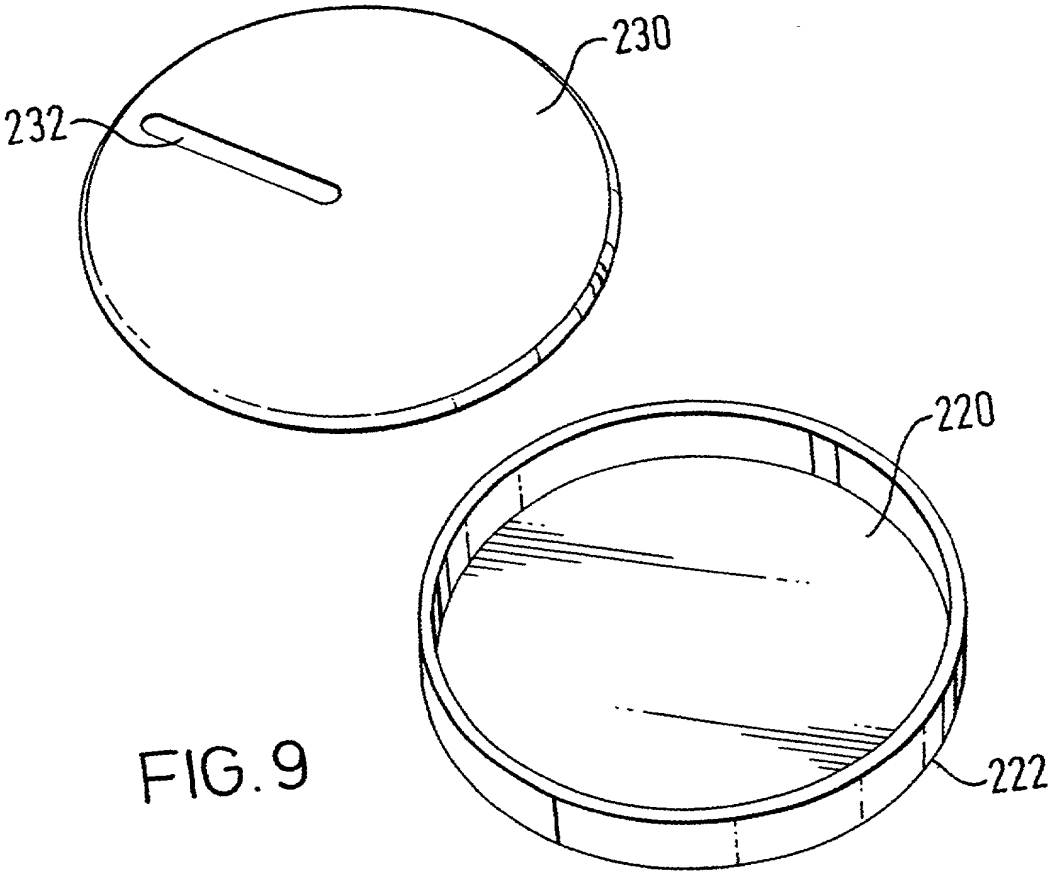

FIG.9

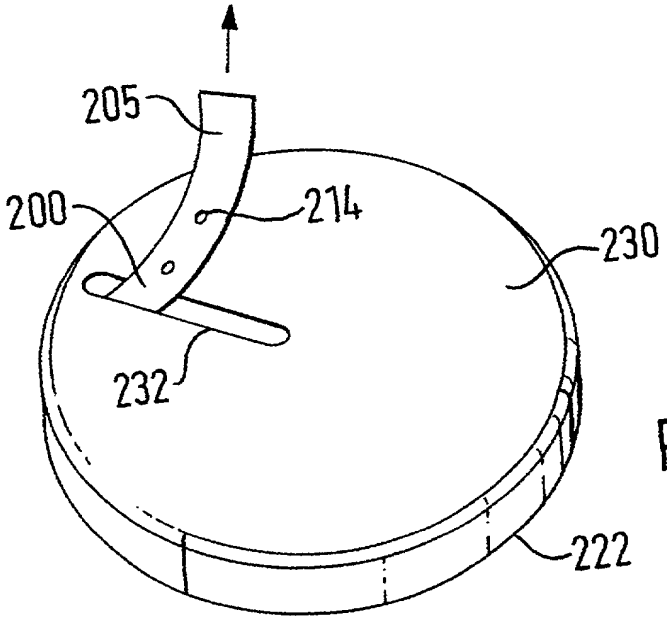

FIG.10

DECLARATION FOR "371" APPLICATION

COMBINED DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION WITH POWER OF ATTORNEY

ATTORNEY'S DOCKET
PG3604USW
First Names Inventor: Paul Kenneth RAND
Complete if known: App No.:
Filing Date
Group Art Unit:

( ) Declaration submitted with initial filing or

( )Declaration submitted after initial filing (surcharge required 37CFR1.16(e))

As below named inventor. I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

INHALATION DEVICE

the specification of which (check only one item below):

[ ]is attached hereto.
OR
[x] was filed on **8 December 1999** as United States application Serial No. _____ or **PCT** International

Application Number **PCT/EP99/09614** filed and was amended on (MM/DD/YYYY) _____(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35, U.S.C. §119 (a)-(d) or §365(b) of any foreign applications(s) for patent or inventor's certificate or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

Prior Foreign Application Number (s)	Country	Foreign Filing Date (MM/DD/YYYY))	PRIORITY CLAIMED
1. 9901282.5	GB	22 January 1999	X
2. 9903342.5	GB	16 February 1999	X
3.			
4.			
5.			

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date (MM/DD/YYYY)	
1.		
2.		
3.		
4.		

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COMBINED DECLARATION FOR UTILITY or DESIGN PATENT APPLICATION WITH POWER OF ATTORNEY

Continued

ATTORNEY'S DOCKET NUMBER: PG3604USW

I hereby claim the benefit under 35, U.S.C. §120 of any United States application or §365(c) of any PCT international application designating the United States of America that is listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. §112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56 which became available between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. PARENT APPLICATION or PCT PARENT APPLICATION

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	STATUS (Check one) PATENTED	PENDING	ABANDONED

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith. (List name and registration number)

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Charles E. Dadswell	Reg. No. 35,851	Virginia C. Bennett	Reg. No. 37,092	John L. Lemanowicz	Reg. No. 37,380
Karen L. Prus	Reg. No. 39,337	Frank P.Grassler	Reg. No. 31,164	Amy H. Fix	Reg. No. 42,616
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PATENT TRADEMARK OFFICE

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919-483-8022

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

2 FULL NAME OF INVENTOR	FAMILY NAME: **RAND**	FIRST GIVEN NAME: **Paul**		SECOND GIVEN NAME/INITIAL: **Kenneth**
INVENTOR'S SIGNATURE	Signature X Paul Kenneth Rand			Date X 17th July 2001
0 RESIDENCE & CITIZENSHIP	CITY: **Ware**	STATE OR FOREIGN COUNTRY: **GB** GBN		COUNTRY OF CITIZENSHIP: **GB**
1 POST OFFICE ADDRESS	POST OFFICE ADDRESS: **GlaxoSmithKline Five Moore Drvie, PO Box 13398**	CITY: **Research Triangle Park**		STATE & ZIP CODE/COUNTRY: **North Carolina 27709, US**
2 FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME		SECOND GIVEN NAME/INITIAL
INVENTOR'S SIGNATURE	Signature			Date
0 RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY		COUNTRY OF CITIZENSHIP
2 POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY		STATE & ZIP CODE/COUNTRY
2 FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME		SECOND GIVEN NAME/INITIAL
INVENTOR'S SIGNATURE	Signature			Date:
0 RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY		COUNTRY OF CITIZENSHIP
3 POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY		STATE & ZIP CODE/COUNTRY

Date